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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,577

07/19/2005

Takanori Uchida

UCHIDA9

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09/01/2006

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EXAMINER

KIM, TAEYOON

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/542,577

Applicant(s)

UCHIDA ET AL.

Examiner

Taeyoon Kim

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 14-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 14-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/18/05.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Claims 1-6 and 14-34 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "previously holds at least" in the 3rd line of the claim do not clearly point out what the subject matter claims. It appears that the fabric contains at least thrombin prior to the addition of fibrinogen to the fabric. However, the claim does not clearly point out the subject matter. For search purpose, the claim is interpreted as "The hemostatic material according to claim 1, wherein the bioabsorbable synthetic nonwoven fabric holds at least thrombin among thrombin and fibrinogen."

2. Claim 6 recites the limitation "Factor XIII" in the 3rd line of the claim. There is insufficient antecedent basis for this limitation in the claim. Factor XIII is not claimed in claim 1. Claim 6 is interpreted without Factor XIII in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6 and 14-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Greenawalt et al. (U.S. Patent 6,056,970; issued on May 2, 2000).

Claims 1-6 and 21-34 are drawn to a hemostatic material (claims 1-6) or a kit (claims 21-34) comprising thrombin and fibrinogen on a bioabsorbable synthetic nonwoven fabric (claims 1, 21 and 29); a limitation to a material for the bioabsorbable synthetic nonwoven fabric is selected from the group consisting of polyglycolic acid, polylactic acid, and a copolymer of glycolic acid and lactic acid (claims 2, 22 and 30); the material being polyglycolic acid (claims 3, 23 and 31); a limitation to the bioabsorbable synthetic nonwoven fabric holds thrombin (claim 4); a limitation to the hemostatic material or kit comprising an additive selected from Factor XIII, a protease inhibitor, or calcium chloride (claims 5, 24 and 32); the additive being calcium chloride (claim 25); the additive being Factor XIII in a container comprising fibrinogen (claims 26 and 33); a limitation to thrombin and fibrinogen being derived from human blood or produced by a genetic recombinant technique (claims 6, 27 and 34); a hemostatic kit comprising a bioabsorbable synthetic nonwoven fabric holding thrombin being made by the method of claim 14 (claim 28)

Claims 14-20 are drawn to a method of preparing a bioabsorbable synthetic nonwoven fabric by the steps of immersing a bioabsorbable synthetic nonwoven fabric into a solution containing thrombin and lyophilizing the obtained nonwoven fabric (claim 14); a limitation to a material for the bioabsorbable synthetic nonwoven fabric is selected from the group consisting of polyglycolic acid, polylactic acid, and a copolymer

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of glycolic acid and lactic acid (claim 15); the material being polyglycolic acid (claim 16); a limitation to the hemostatic material comprising an additive selected from Factor XIII, a protease inhibitor, or calcium chloride (claim 17); calcium chloride of claim 17 being fixed to the bioabsorbable synthetic nonwoven fabric with thrombin (claim 18); Factor XIII being added to fibrinogen (claim 19); thrombin, fibrinogen and Factor XIII being derived from human blood or a produced by a genetic recombinant technique (claim 20).

Greenawalt et al. teach a composition, a method and a kit comprising hemostatic compounds such as thrombin, fibrinogen, Factor XIII, protease inhibitors and calcium chloride, along with a bioabsorbable synthetic polymer (nonwoven fabric) made of polyglycolide (polyglycolic acid), polylactide (polylactic acid) or copolymers thereof (columns 2-4).

Greenawalt et al. also teach thrombin and fibrinogen are derived from human plasma or synthetic forms produce by recombinant DNA technology (column 3, lines 52-64; claims 4 and 9).

Greenawalt et al. also teach the bioabsorbable fabric containing thrombin and fibrinogen is made by mixing thrombin, fibrinogen and bioabsorbable polymers in organic solvent and then drying (lyophilizing) the combination (column 5, lines 5-11 and 29-46; claims 6-8).

Greenawalt et al. teach a hemostatic kit containing multiple hemostatic compositions in a separate package (column 6, lines 51-55).

Thus, the reference anticipates the claimed subject matter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 14-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-8 of copending Application No. 10/534,715. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a method/process of preparing a bioabsorbable synthetic nonwoven fabric holding thrombin by the same steps and the same material. Therefore, the claims of '715 application anticipate the claims of the current application as such the application claims render obvious the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

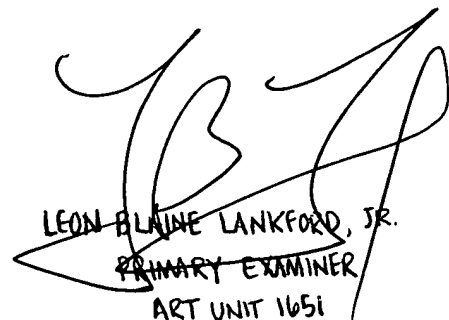
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim
Patent Examiner
Art Unit 1651


LEON BLAINE LANKFORD, JR.
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